Supreme Court, U.S.
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No. ~~05-15832~~

IN THE
SUPREME COURT OF THE UNITED STATES

MAXIMUM COMFORT, INC.,

Petitioner

v.

SECRETARY OF HEALTH & HUMAN SERVICES, et al.,

Respondent

On Petition for Writ of Certiorari
To the United States Court
of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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Question Presented

Whether the Secretary of Health and Human Services ("Secretary") is entitled to deny Medicare reimbursement to suppliers of durable medical equipment on the ground that the Medicare beneficiary's physician signed a Secretary designated Certificate of Medical Necessity swearing to the necessity of the patient receiving the equipment but subsequently the physician failed during an audit to provide the beneficiary's medical records to the Secretary.

Parties to the Proceedings

The petitioner in this case is Maximum Comfort, Inc. The other parties in this case are The Secretary of Health & Human Services; Michael O Leavitt. There are no parties to the proceedings other than those named in the Petition. Maximum Comfort, Inc. does not have a parent corporation. No publicly held company owns ten percent (10%) or more of Maximum Comfort stock.

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PETITION FOR WRIT OF CERTIORARI

The petitioner, Maximum Comfort, Inc. respectfully petitions this court for a writ of certiorari to review the judgment and opinion of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the United States Court of Appeals for the Ninth Circuit to which this petition relates was filed on December 21, 2007 and is attached as Appendix A. It is reported at *Maximum Comfort, Inc. v. Secretary of Health & Human Services, et al.*. 512 F.3d 1081 (9th Cir. 2007). The opinion and judgment of the District court granting summary judgment and permanent injunction is attached as Appendix B. It is reported at *Maximum Comfort, Inc. v. Thompson* 323 F. Supp. 2d 1060 (E.D. Cal. 2004).

JURISDICTION

The judgment at the Court of Appeals was entered on December 21, 2007. This petition is filed within 90 days of that date. Rule 13.1. Petitioner invokes the court's jurisdiction under 28 U.S.C. Section 1254(1).

STATUTES AND REGULATIONS INVOLVED

42 U.S.C. Section 1392m(j).

STATEMENT OF CASE

Petitioner, Maximum Comfort, Inc., ("Maximum") is a California corporation in the business of selling, leasing, and renting durable medical equipment ("DME"). App. B 2. Petitioner supplies DME, including motorized wheelchairs to Medicare and Medicaid beneficiaries. App. B 2. Medicare reimburses Maximum for qualifying DME supplied to Medicare beneficiaries. App. B 2. To receive reimbursement Maximum first submits invoices to and receives approval from CIGNA Health care ("CIGNA"), a private fiscal agent that contracted with Medicare to process claims. App. B 2.

The dispute in this case involves reimbursement claims for motorized wheelchairs provided by Maximum to beneficiaries. For each beneficiary Maximum obtained a Certificate of Medical Necessity ("CMN") signed by the beneficiary's physician documenting the medical necessity of the DME. App. B 2. Maximum submitted each claim and CIGNA initially approves the claims and Medicare reimbursed Maximum. App. B 2.

However, after an audit, CIGNA determined that although Maximum had obtained a signed CMN, it had not obtained the beneficiary's physician's records and that the claims were therefore not sufficiently documented. App. B 2. CIGNA determined that the wheelchairs did not qualify for Medicare and that Maximum had been overpaid. CIGNA began recouping the alleged overpayments by offsetting Maximum's Medicare account. App. B 2.

Maximum unsuccessfully challenged the determination through CIGNA's in-house administrative appeals process. It appealed and two different Administrative Law Judges ("ALJ's") issued

almost identical decisions in Maximum's favor concluding that Maximum was only required to submit a CMN to establish the medical necessity and reasonableness of the wheelchairs. The ALJ's concluded that the Secretary did not have the authority to require Maximum to provide physician and medical records. App. B 8.

The Medical Appeals Counsel ("MAC"), on its own motion, reversed the ALJ's decisions. In its opinion it concluded that the Secretary, through its carrier, could require documentation in addition to the CMN. App. B 8.

Maximum sought review of MAC's decision in the District court pursuant to 42 U.S.C. Section 405(g). App. B 3,10. On cross motions for summary judgment the court granted Maximum's motion and issued a permanent injunction enjoining the Secretary from recouping the alleged overpayments. In reaching its decision, the trial court stated that "A review of the statute [42 U.S.C. Section 1395m(j)(2)(B)] demonstrates that, contrary to the Secretary's contentions, there is no gap left by Congress for the Secretary to fill regarding medical

necessity documentation." App. B14. The trial court determined that under the two step process mandated by *Chevron USA, Inc. v. National Resources Defense Counsel, Inc.* 467 U.S. 837, 104 S.Ct. 278, 81 L.Ed.2d 694 (1984) the intent of Congress was clear and that the Secretary must give effect to the unambiguously expressed intent of Congress.

On appeal, the United States Court of Appeals for the Ninth Circuit reversed the decision of the trial court and remanded for further process. The appellate court concluded that the Secretary could require, as a condition of reimbursement to an equipment supplier, information in addition to that provided by the CMN. The court rejected the trial court's position that 42 U.S.C. Section 1395m(j)(2) precluded the Secretary from requiring additional documentation from the supplier, beyond the CMN, to establish medical necessity for equipment supplied.

REASONS FOR GRANTING THE PETITION

This court should grant the petition because the appellate court incorrectly found that the

Secretary had the authority, through its contracted carriers, to require documentation of medical necessity in addition to the CMN despite the clear mandate of 42 U.S.C. Section 1395m(j)(2)(B) that the CMN was the sole documentation allowed to document medical necessity.

A court's review of an agency's construction of a statute involves a two step process. First, it must determine whether the statute speaks directly to the issue; if so, no further construction is required. *Chevron USA v. National Resources Defense Counsel, Inc., supra,* 467 U.S. 837. In the present case, Congress clearly addressed the issue of medical necessity documentation in 42 U.S.C. Section 1395m(j)(2). Subdivision (2) of that section provides that:

> "Certificates of Medical Necessity
> (A) Limitation on information provided by suppliers on certificates of medical necessity.
> (i) In general.
> ...[A] A supplier of medical equipment and supplies

may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary...

(B) Definition.

For purposes of this paragraph, the term 'certificate of medical necessity' means a form or

other document containing information and required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis and treatment of illness or entry or to improve the functioning of a malformed body member."

This section plainly specifies that Congress intended that whatever information may be required by carriers from suppliers to show the medical necessity and reasonableness of DME must be contained in the CMN.

The CMN created and approved by the Secretary in effect at the time in question was comprised of four sections. Section A solicited identifying information of the supplier, beneficiary, and physician, as well as other administrative information. Section B contained a series of questions to be completed by the beneficiary's ordering physician. According to the instructions for

completing the CMN, Section B was 'used to gather clinical information to determine medical necessity'. Section C of the CMN required the supplier to provide a narrative description of the equipment and the cost thereof. Section D provided for the physician's attestation and signature. The instructions explained that the physician's signature certified "the items ordered are medically necessary for [the] patient". App. B 14. The CMN therefore complied with Congress' mandate that whatever clinical information the carrier determined was required to determine the medical necessity of motorized wheelchairs must be gathered using the CMN.

The rule adopted by the Secretary in violation of the clear mandate of Section 1395m(j) works a great injustice on Maximum. Providers of DME have no authority or power to compel a beneficiary's physician to provide medical records to the provider. Maximum therefore provided DME to beneficiaries based upon a signed CMN which attested to the medical necessity of the DME and then, on a subsequent audit, was denied payment based upon Maximum's inability to provide the beneficiary's

medical records. Maximum's claims were not denied because the audit disclosed that the wheelchairs were not medically necessary, they were denied because Maximum could not provide documents which it neither had or could obtain.

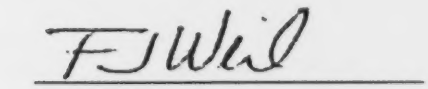
CONCLUSION

The petition for a writ of certiorari should be granted.

Dated: March 19, 2008

Respectfully submitted,

WELLS, SMALL,
FLEHARTY & WEIL



FREDERICK J. WEIL
Attorney for Maximum
Comfort, Inc.
Petitioner

APPENDICES
A, B, AND C

APPENDIX A

FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

MAXIMUM COMFORT, INC., Plaintiff-Appellee, v. SECRETARY OF HEALTH AND HUMAN SERVICES; MICHAEL O. LEAVITT, * Defendants-Appellants.	No. 05-15832 D.C. No. CV-03-01584-LKK OPINION

Appeal from the United States District Court
for the Eastern District of California
Lawrence K. Karlton, Senior Judge, Presiding

Argued and Submitted
June 13, 2007—San Francisco, California

Filed December 21, 2007

Before: Mary M. Schroeder, William C. Canby, Jr. And M. Margaret McKeown, Circuit Judges.

Opinion by Judge Canby

*Michael O. Leavitt is substituted for his predecessor, Tommy G. Thompson, as Secretary of Health and Human Services. Fed. R. App. P. 43(c)(2).

David C. Frederick, Kellogg, Huber, Hansen, Todd, Evans & Figel, P.L.L.C., Washington, D.C., for the plaintiff-appellee.

OPINION

CANBY, Circuit Judge:

Appellant, the Secretary of Health and Human Services, administers the federal Medicare program. Appellee Maximum Comfort, Inc. supplies power-operated wheelchairs to Medicare beneficiaries. The Secretary determined that Maximum Comfort was not entitled to reimbursement for equipment it supplied to certain Medicare beneficiaries, because the company did not establish sufficiently that the power wheelchairs were medically necessary. Maximum Comfort sought judicial review of the Secretary's determination, and the district court reversed. The Secretary now appeals.

The primary question before us is whether Maximum Comfort, by submitting for each wheelchair, a "certificate of medical necessity"[1] signed

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[1]The parties and the decisions under review all use the initials CMN in place of "certificate of medical necessity." For ease of comprehensible reading, we will avoid use of the initials except where inclusion in quoted material compels it. In the same

by a physician, established conclusively that the wheelchair was medical necessary, thus precluding the Secretary from requiring additional documentation. Like the two other circuit courts have addressed the question, we conclude that the applicable provisions of the Medicare Act do not make the certificate conclusive, and that the Secretary may require additional documentation to establish medical necessity. *See MacKenzie Medical Supply, Inc. v. Leavitt,* No. 06-1630, 2007 WL 3173302 (4th Cir. Oct. 31, 2007); *Gulfcoast Medical Supply, Inc. v. Secretary, HHS,* 468 F. 3d 1347 (11 Cir. 2006). We accordingly reverse the decision of the district court.

I. BACKGROUND: PART B OF THE MEDICARE ACT

The Medicare Act, established under Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395hhh, provides coverage for certain medical services to eligible aged and disabled people. The Medicare Program is administered by the Centers for

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spirit, we avoid entirely the use of DME for "durable medical equipment."

Medicare and Medicaid Services, on behalf of the Department of Health and Human Services. Part B of the Medicare Act provides supplementary medical insurance for, *inter alia*, covered medical supplies, including durable medical equipment such as power-operated wheelchairs. 42 U.S.C. §§ 1395j-1395w-4.

In administering Part B, the Centers act through private entities, such as insurance companies, called "carriers."[2] Claims for durable medical equipment are processed by designated regional carriers. *See* 42 U.S.C. §§ 1395 m(a)(12), 1395u. Upon receipt of a claim for such equipment, the carrier pays the Medicare beneficiary on the basis of an itemized bill, or pays the Medicare supplier on the basis of an assignment of benefits from the beneficiary. 42 U.S.C. § 1395u(b)(3)(B).

In order for the beneficiary, and therefore the equipment supplier, to be reimbursed for a claim,

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[2]These carriers also are referred to as "medicare administrative contractors" in recent amendments to the Medicare Act. *See* Pub. L. No. 108-173, 117 Stat. 2066, 2384 (2003).

Medicare requires the beneficiary's physician to certify that the services provided were medically required. 42 U.S.C. § 1395n(a)(2); *see also* 42 U.S.C. § 1395y(a)(1)(A) (Medicare coverage is limited to services that are medically "reasonable and necessary"). In connection with the processing of claims, an equipment supplier "may distribute to physicians" a "certificate of medical necessity," which the statute defines as "a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395m(j)(2). Suppliers may include on the certificate only certain information, such as identifying information about the supplier, the beneficiary, the equipment being supplied, and other administrative information unrelated to the beneficiary's medical condition. *Id.* The remaining information is completed by the beneficiary's physician. If the Secretary requires a supplier of durable medical equipment to provide diagnostic or other medical information in order for

payment to be made, the physician "shall provide that information to the entity at the time that the item [ ] is ordered . . . ." 42 U.S.C. § 1395u(p)(4).

"For reasons of administrative efficiency, carriers typically authorize payment on claims immediately upon receipt of the claims, so long as the claims do not contain glaring irregularities." *Gulfcoast*, 486 F.3d at 1349. Carriers later may conduct audits to ensure that payments were made in accordance with Medicare criteria. If the carrier discovers that payments were made for equipment not covered by the Medicare Act, it may assess an overpayment and recoup the overpaid amount from the supplier. 42 C.F.R. § 405.371(a). Suppliers, however, may be excused from liability for repayments when they did not have reason to know the equipment they supplied would not be covered by Medicare. 42 U.S.C. § 1395pp. Suppliers also may appeal carriers' claim resolutions through a designated administrative appeals process, 42 U.S.C. § 1395ff(b)(1)(A), and, after exhausting the administrative appeals process, may seek judicial review in federal court pursuant to the

Administrative Procedure Act. *Id.*; 42 U.S.C. § 405(g).

II. FACTS

In 1998 and 1999, Maximum Comfort provided numerous power-operated wheelchairs to Medicare beneficiaries in California, Oregon, and Nevada. CIGNA Healthcare, the designated regional carrier, initially approved the claims for these power-operated wheelchairs, and Medicare accordingly reimbursed Maximum Comfort. CIGNA then conducted an audit of 30 of the 236 power-operated wheelchair claims submitted by Maximum Comfort in 1998 and early 1999. CIGNA concluded that Maximum Comfort had failed to substantiate the medical necessity of 22 of the 30 claims at issue, and concluded from this sample that Maximum Comfort had been overpaid $640,457.01. This amount was reduced to $548,555.04 once Maximum Comfort provided CIGNA with additional documentation. CIGNA then conducted a second audit, examining 182 Medicare claims submitted by Maximum Comfort from mid-1998 to mid-1999. CIGNA concluded that Maximum Comfort was overpaid $237,229.11, again

because it failed to provide documentation establishing the medical necessity and reasonableness of the wheelchairs.[3]

Maximum Comfort unsuccessfully appealed both overpayment assessments through CIGNA's in-house administrative process. The examining officer upheld CIGNA's overpayment assessments, finding that the certificates submitted by Maximum Comfort failed to demonstrate the medical necessity of power wheelchairs, and that either Maximum Comfort failed to seek additional documentation of medical necessity or the beneficiaries' physicians had

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[3] The applicable regional supplier's manual provides that a power wheelchair is covered by Medicare when all of the following criteria are met:

1) The patient's condition is such that without the use of a wheelchair, he would be bed or chair confined...and;

2) The patient's condition is such that a wheelchair is medically necessary and the patient is unable to operate the wheelchair manually, and;

3) The patient is capable of safely operating the controls for the power wheelchair.

DMERC Region D Supplier Manual, Ch. IX, p. 52.

not responded to requests for additional documentation.[4]

Maximum Comfort then appealed CIGNA's decisions to two Administrative Law Judges ("ALJs") pursuant to 42 C.F.R. § 405.855. The ALJs ruled in Maximum Comfort's favor, finding that (1) for each of the claims at issue, the beneficiary's treating physician had completed a valid certificate of medical necessity certifying that a power wheelchair was reasonable and necessary for the diagnosis or treatment of the beneficiary's injury or the functioning of a malformed body member; and (2) the wheelchairs furnished by Maximum Comfort were medically reasonable and necessary and met the requirements for coverage under Part B of the Medicare Act. In reaching finding (2), the ALJs concluded that a certificate of medical necessity alone sufficed to prove the medical necessity of durable

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[4]In other cases not at issue in this appeal, the officer found that both the certificates or medical necessity and the additional medical documentation submitted to CIGNA did not sufficiently demonstrate the medical necessity of power wheelchairs.

medical equipment.

The Medicare Appeals Council *sua sponte* reviewed the ALJs' decisions and reversed both of them. The Council concluded that Congress did not intend the certificate to be the only mechanism through which suppliers could establish coverage for durable medical equipment, and that nothing prevented the Secretary from imposing additional documentation requirements on equipment suppliers. The Council found that the certificates in issue failed to establish medical necessity, and that Maximum Comfort consequently was not entitled to reimbursement.

The Council also found that certain manuals and newsletters issued by CIGNA instructed Maximum Comfort to retain supporting documentation substantiating its equipment claims in case of an audit. As a result, the Council concluded that Maximum Comfort knew or should have known that its claims were deficient and therefore it was not entitled under 42 U.S.C. § 1395pp to a waiver of its repayment liability.

Maximum Comfort then brought this action challenging the Appeal Council's decision pursuant to the Administrative Procedure Act. *See* 42 U.S.C. §§ 405(g), 1395ff(b). On cross-motions for summary judgment, the district court ruled in favor of Maximum Comfort. The court found that the plain language of § 1395m(j)(2)(A)(i) establishes that "any and all information required from suppliers to make a medical necessity determination must be contained in a CMN." *Maximum Comfort, Inc. v. Thompson*, 323 F. Supp. 2d 1060, 1075 (E.D. Cal. 2004). The court further found that the Secretary could not require suppliers of durable medical equipment to obtain additional documentation of medical necessity. *Id.* at 1074-75. As a result, the district court permanently enjoined the Secretary from collecting overpayments from Maximum Comfort in connection with the audited claims. *Id.* at 1075. This appeal followed.

III. DISCUSSION

A. Whether the certificate of medical necessity is conclusive proof of medical necessity

The first question before us is one of statutory construction: whether the Medicare Act requires the

Secretary to base his decision that an item of durable medical equipment is or is not "medically reasonable and necessary" solely on the contents of a certificate of medical necessity, or whether the Secretary may request additional documentation from a supplier of durable medical equipment. The two-step approach of *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), governs our inquiry. We first ask whether the Medicare Act speaks directly to the question presented. "If the intent of Congress is clear, that is the end of matter," and this court must give effect to Congress's expressed intent. *Id.* at 842-43. If, on the other hand, the Medicare Act is silent or ambiguous with respect to the question presented, then this court asks "whether the [Secretary's] answer is based on a permissible construction of the statute." *Id.* at 843.

We begin with the statute's plain language. *See Botosan v. Paul McNally Realty*, 216 F.3d 827, 831 (9th Cir. 2000). The provisions on which Maximum Comfort (and the district court) relied state:

(2) Certificates of medical necessity

(A) **Limitation on information provided by suppliers on certificates of medical necessity**

(i) **In general**

"[A] supplier of medical equipment and supplies may distribute to physicians...a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition)

identified by the Secretary.

. . .

(B) Definition

For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

42 U.S.C. § 1395m(j)(2)(A) & (B).

[1] Maximum Comfort draws from these provisions a command that the Secretary must accept the certificate of medical necessity as conclusive for purposes of reimbursing the equipment supplier. For reasons that parallel the reasoning of the Fourth Circuit in *MacKenzie*, 2007 WL 3173302 at *6-7, and the Eleventh Circuit in *Gulfcoast*, 468 F.3d at 1351-52, we reject this

interpretation of § 1395m(j)(2). The language of the statute contains no such command or limitation. The first provision, § 1395m(j)(2)(A)(I), states that "a supplier of medical equipment and supplies *may* distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity. . . ." (emphasis added). This subsection permits (but does not require) the supplier to distribute certificates to physicians or patients. It also limits the information suppliers may furnish in the certificate of medical necessity, but does not purport to explain the effect to be given a completed certificate or suggest that a completed certificate is sufficient and conclusive proof of medical necessity. *See MacKenzie*, 2007 WL 3173302 at *6.

[2] The second subsection, § 1395m(j)(2)(B), provides that "*[f]or purposes of this paragraph*, the term 'certificate of

medical necessity' means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary. . . ." (emphasis added). The most logical reading of this sentence is that it is intended only to define the certificate of medical necessity for the purposes of applying the restrictions outlined in § 1395m(j)(2)(A).[5] The subsection does not state that the certificate of medical necessity is the *sole* vehicle for claims reimbursement, nor does it state that a completed certificate establishes, by itself, a right to reimbursement. *See MacKenzie*,

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[5]The legislative history of this statute supports this interpretation. As the Appeals Council noted in its decision, § 1395m(j) was added to the statute to modify previous restrictions that, inter alia, prohibited suppliers from completing *any* portion of the certificate of medical necessity. *See* Social Security Amendments of 1994, Pub. L. No. 103-432, 108 Stat. 4398, 4416-19 (1994).

2007 WL 3173302 at *6; *Gulfcoast*, 468 F.3d at 1351.

[3] We reject, therefore, Maximum Comfort's view that § 1395m(j)(2) precludes the Secretary from requiring additional evidence, beyond the certificate, to establish medical necessity for equipment supplied. Not only do the plain words of § 1395m(j)(2) fail to impose any such restraint upon the Secretary, but reading such a limitation on the Secretary's powers into that provision would be inconsistent with § 1395y(a), which states:

> *Notwithstanding any other provision of this subchapter*, no payment may be made under Part A or Part B of this subchapter for any expenses incurred for items or services—
> (1)(A) which . . . are not reasonable and necessary

for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. . . . (emphasis added). By the terms of this provision, §1395m(j)(2) as an "other provision of this subchapter" cannot limit the Secretary's duty imposed by § 1395y(a) to ensure that no payment is made for items that are not medically necessary.

[4] We conclude, therefore, that the Secretary's interpretation of the of the relevant provisions of the Medicare Act is correct, and that the Secretary may require, as a condition of reimbursement to an equipment supplier, information in addition to that provided by the certificate of medical necessity. If there

could be any doubt about the meaning of § 1395m(j)(2) in light of § 1395y(a), however, the provision would at worst be silent or ambiguous with regard to the Secretary's power to require additional information. In that case, for reasons that should be apparent from our discussion of the statutory provisions in issue, the interpretation of the Secretary is certainly reasonable and entitled to deference under *Chevron*, 467 U.S. at 842-43. *See MacKenzie*, 2007 WL 3173302 at *7; *Gulfcoast*, 468 F.3d at 1352-53.

B. Whether Maximum Comfort was on notice that payment would be denied

[5] We now turn to whether Maximum Comfort is excluded from liability for repayment under 42 U.S.C. § 1395pp(a)(2), which provides that the company may not be denied reimbursement if it "did not know, and could not reasonably have been expected

to know, that payment would not be made" for the durable medical equipment it supplied.[6] We may set aside the Secretary's conclusion that Maximum Comfort is not excused from liability under § 1395pp(a)(2) if it "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." *See Indep. Acceptance Corp. v. California*, 204 F.3d 1247, 1251 (9th Cir. 2000) (quoting 5 U.S.C. § 706(2)(A); (E)) (internal quotation marks omitted). Our review of the Secretary's decision is "highly deferential." *Id.*

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[6]Because the district court concluded that Maximum Comfort could rely on the certificate alone to establish medical necessity, it did not address Maximum Comfort's eligibility for limitation of liability under 42 U.S.C. § 1395pp(a)(2). We reach the issue, however, because we review do novo the district court's decision, *see Indep. Acceptance Corp. v. California*, 204 F.3d 1247, 1251 (9th Cir. 2000), and because the § 1395pp(a)(2) issue was decided by the Secretary and was presented to the district court for review.

[6] Under Health and Human Services regulations, Maximum Comfort is deemed to have constructive notice of manual issuances, bulletins, and other written guidelines and directives indicating that certain itesm of durable medical equipment will not be covered by Medicare. *See* 42 C.F.R. § 411.406(e). CIGNA's Supplier Manual states that physicians are required to maintain documentation of medical necessity beyond the certificate of medical necessity.[7] A March 1997

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[7]The manual states:

> The physician must be certain that the patient's *medical record* contains sufficient documentation of the patient's medical condition to substantiate the need for the items ordered. . . Although it is recommended that a copy of the completed CMN be kept in the patient's record, the CMN by itself does not provide sufficient documentation of medical necessity. There must be additional clinical information in the medical record. The physician must also obtain a copy of the order or have equivalent information in the record.

CIGNA newsletter makes clear that, because physicians are not subject to liability under the applicable statutes and regulations, it is the responsibility of the supplier to establish medical necessity "either through the order physician or through some other means." Region DMERC Diaglogue Mar. 1997 p. 8. An earlier CIGNA newsletter, in a section entitled "Retaining CMN Records," states that, in the course of an audit, "[s]upporting documentation will be requested and reviewed from the selected suppliers by the CMN validation auditors." Region DMERC Dialogue July 1995 p. 8. These documents provided Maximum Comfort with sufficient notice that the Secretary might require documentation of medical necessity in addition to the certificate of

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DMERC Region D Supplier Manual, Ch. VII, p. 3 (emphasis in original).

medical necessity and would deny the claim if the additional information were not forthcoming. *See* 42 U.S.C. § 1395pp(a)(2); *MacKenzie*, 2007 WL 3173302 at *7. We accordingly uphold the Secretary's conclusion that Maximum Comfort cannot avail itself of the liability-limiting provisions of § 1395pp(a)(2).

IV. CONCLUSION

The judgment of the district court is reversed, and the matter is remanded to the district court for further proceedings consistent with the opinion.

REVERSED AND REMANDED.

COUNSEL

Howard S. Scher, Assistant United States Attorney, Civil Division, Washington, D.C., for the defendants-appellants.

APPENDIX B

FILED

Jun 30 2004

Clerk, U.S. District Court
Eastern District of California
By_____
Deputy Clerk

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

MAXIMUM COMFORT, INC., a California corporation,
Plaintiff,

NO. CIV. S-03-1584 LKK/PAN

v.

ORDER
TO BE PUBLISHED

TOMMY G. THOMPSON, Secretary of Health and Human Service of the United States,
Defendant.

Plaintiff filed this complaint against the Secretary of the United States Department of Health and Human Services, Tommy G. Thompson ("Secretary"), seeking judicial review of a final administrative decision made by the Medicare Appeals Council ("MAC") of the Department of Health and Human Services. The matter comes before the court on the parties' cross-motions for summary judgment. I decide the motions on the basis of the papers and pleadings filed herein and after oral argument.

I.

BACKGROUND

Plaintiff, Maximum Comfort, is a California corporation in the business of selling, leasing, and renting durable medical equipment ("DME"). Plaintiff supplies DME, including motorized wheelchairs, to Medicare and Medicaid beneficiaries throughout California, Oregon and Nevada. Medicare reimburses Maximum Comfort for qualifying DME supplied to its beneficiaries. To receive reimbursement, plaintiff must first submit invoices to and receive approval from CIGNA

Healthcare, a private fiscal agent that has contracted with Medicare to process claims.

The dispute in this case concerns reimbursement claims for numerous motorized wheelchairs provided by plaintiff to Medicare beneficiaries. CIGNA initially approved the claims for the motorized wheelchairs and Medicare accordingly provided plaintiff with reimbursement payments. After CIGNA conducted an audit, however, it concluded that the wheelchairs did not qualify for coverage and that Medicare had therefore overpaid plaintiff. Consequently, CIGNA began recouping the payments for the disqualified claims by offsetting plaintiff's Medicare account. Plaintiff challenged CIGNA's decision and exhausted the appeals process. In the final administrative hearing, the MAC concluded that the wheelchairs could not be paid for by Medicare because plaintiff had insufficiently documented the medical necessity of the wheelchairs.

A. PROCEDURAL HISTORY

This case was first heard by this court on October 20, 2003, pursuant to plaintiff's motion for a

preliminary injunction. On October 22, the court issued an order explaining that the parties had failed to address certain critical issues and directed them to file supplemental briefing. In that same order, the court enjoined the defendant from "[r]ecouping, offsetting or otherwise collecting from plaintiff any alleged overpayments for any of the beneficiaries which are the subject of this action from any amount due and owing to plaintiff and from failing to pay such amount when due." Order at 3. The parties filed their supplemental briefing and then filed cross-motions for summary judgment. In due course, a hearing was set and oral argument was heard on the cross-motions. This opinion disposes of all of the pending matters before the court.

B. THE MEDICARE PROGRAM

The Medicare Act, established under Title 18 of the Social Security Act, 42 U.S.C. §§ 1395-1395gg, pays for covered medical care provided to eligible aged and disabled persons. The Medicare Program is administered by the Centers for Medicare and Medicaid Services ("CMS"), a component of the United States Department of Health and Human

Services ("HHS").[1]

The Medicare Act consists of three main parts: Part A, which generally authorizes payment for covered inpatient hospital care and related services, 42 U.S.C. §§ 1395c to 1395i-5, 42 C.F.R. Part 409; Part B, which provides supplementary medical insurance for covered medical services and equipment, 42 U.S.C. §§ 1395j to 1395w-4, 42 C.F.R. Part 410; and Part C, which authorizes beneficiaries to obtain covered services through HMOs and other "managed care" arrangements, 42 U.S.C. §§ 1395w-21 to 1395w-28, 42 C.F.R. Part 422.

This case involves Part B of the Medicare Act. Part B resembles "a private medical insurance program that is subsidized in major part by the federal government."[2] Schweiker v. McClure, 456

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[1] CMS was formerly known as the Health Care Financing Administration ("HCFA"). See 66 Fed. Reg. 36583, 36584 (July 12, 2001).

[2] Part B participants pay monthly premiums that are deposited along with federal appropriations in the Federal Supplementary Medical Insurance Trust Fund which finances Part B. See 42 U.S.C. §§ 1395j, r, s, t, w.

U.S. 188, 190 (1982). Coverage under this part extends to DME, including wheelchairs used in a patient's home. 42 U.S.C. §§ 1395k, 1395x(s), 1395x(n); 42 C.F. R. § 410.38(a)-(c). As with private medical insurance programs, the statute and its implementing regulations establish conditions and limitations on the coverage of services and equipment, 42 U.S.C. §§ 1395k, 1395l, 1395x(s), and provide exclusions from coverage. 42 U.S.C. § 1395y(a)(2)-(16); 42 C.F.R. § 411.15(a)-(j). In all cases, Medicare coverage is limited to services that are medically "reasonable and necessary" for the diagnosis or treatment or illness. 42 U.S.C. § 1395y(a)(1)(A); 42 C.F.R. § 411.15(k)(1).

C. MEDICARE CARRIERS

In administering Part B, CMS acts through private fiscal agents called "carriers." 42 U.S.C. § 1395u; 42 C.F.R. Part 421, Subparts A and C; 42 C.F.R. § 421.5(b). Carriers are entities that, under contract with the Secretary, perform a variety of functions including making coverage determinations, determining reimbursement rates and allowable payments, conducting audits of the claims submitted

for payment, and rejecting or adjusting payment requests. Claims for DME, prosthetics, and orthotics are processed by designated regional carriers called Durable Medical Equipment Regional Carriers ("DMERCs"). 42 U.S.C. §§ 1395m, 1395u; 42 C.F.R. § 421.210. At all relevant times, the DMERC for Maximum Comfort was CIGNA Healthcare ("CIGNA").

One of the carrier's duties is to conduct post-payment audits to ensure that payments are made in accordance with applicable Medicare payment criteria. When payment is made erroneously, an "overpayment" is assessed and "recouped" from subsequent payments due to the DME supplier.[3] 42 C.F.R. § 421.200(a)(2); see also 42 U.S.C. §§ 1395g(a), 1395l(j), 1395gg (b)(1); 42 C.F.R. §§ 405.370, 405.371(a)(1), (2), 405.350. The Act provides for relief from liability for a supplier when it is determined

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[3] Recoupment is defined as "[t]he recovery by Medicare of any outstanding Medicare debt by reducing the present or future Medicare payments and applying the amount withheld to the indebtedness.: 42 C.F.R. § 405.370.

that the supplier "did not know, and could not reasonably have been expected to know, that payment would not be made for a service in question." 42 U.S.C. § 1395pp(a).

D. DURABLE MEDICAL EQUIPMENT SUPPLIERS.

Private businesses selling health care items and products may enter into agreements with the Secretary to become participants in the Medicare program. See 42 U.S.C. § 1395u(h)(1). Once participants, these business, identified by Medicare as suppliers, can provide hardware to Medicare beneficiaries. Beneficiaries execute an assignment of benefits to the supplier so that it may be reimbursed for the service by Medicare.[4] See 42 U.S.C. § 1395u (b) (3) (B). A prerequisite for receipt of reimbursement is submitting a Certificate of Medical Necessity (CMN) to the Carrier. See 42 U.S.C. §

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[4] Under an assignment agreement, the beneficiary transfers his right to payment to the supplier. A supplier who accepts assignment agrees to accept, as full satisfaction, the amount the carrier determines to be the reasonable charge. See 42 U.S.C. § 1395u(b) (3) (B) (ii); 42 C.F.R. § 424.55.

1395m (j) (2) (A).

II.

FACTS

On April 3, 2000, CIGNA audited 30 of the 236 power-operated wheelchair claims submitted by plaintiff from its Redding store between January 1, 1998 and January 22, 1999. Administrative Record (A.R.) Vol. 6 at 1585. This audit, identified as the "Hayes group" audit,[5] resulted in a determination that plaintiff failed to provide sufficient medical information, including patients' medical records, to substantiate the medical necessity of 22 reimbursement claims. As a result, CIGNA concluded that Maximum Comfort was overpaid a total of $640,457.01.[6] Id. at 1595. CIGNA

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[5] Brenda Hayes was the designated lead Medicare beneficiary in the Administrative Law Judge's review of this group of claims audit, referred to as the 'Hayes group' claims throughout the record.

[6] CIGNA used a method it refers to as "extrapolation" to project the overpayments of the 22 claims to the balance of the 236 claims to arrive upon an original overpayment assessment of $640,457.01.

subsequently received additional documentation from the plaintiff, reducing the number of problematic claims to 19 and the overpayment amount to $548,555.04. Id. At 1634.

On September 4, 2000, CIGNA notified plaintiff that it conducted a second audit of a sample number of the 182 Medicare claims submitted by plaintiff from its Sacramento store between July 1, 1998 and July 2, 1999. A.R. Vol. 5 at 1275. This second audit, known as the "Torres group," [7] resulted in a determination that plaintiff was overpaid $237,229.11. A.R. Vol. 4 at 1180. [8] CIGNA determined that the claims did not qualify for reimbursement because, although plaintiff submitted the required CMN for each claim in the Hayes and Torres groups, it failed to provided *additional*

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[7] Elizabeth Torres was the designed lead Medicare beneficiary in the Administrative Law Judge's review of this group of claims, referred to as the "Torres group" throughout the record.

[8] The original overpayment assessment was in the amount of $308,383.50, but was subsequently reduced to $237,229.11. A.R. Vol. 4 at 1181; A.R. Vol. 5 at 1275-1279.

medical documentation to establish the medical necessity and reasonableness of the motorized wheelchairs. A.R. Vol. 5 at 1251; A.R. Vol. 6 at 1585.

Plaintiff challenged both of the overpayment assessments through CIGNA's in-house administrative appeals process, but did not prevail. A.R. Vol. 3 at 572; A.R. Vol. 5 at 1335; see 42 C.F.R. §§ 405.815, 405.821. It then appealed CIGNA's decisions. A.R. Vol. 1 at 20, 22; see 42 C.F.R. § 405.855. Two different Administrative Law Judges (ALJs) issued almost identical decisions in plaintiff's favor, concluding that, as a supplier, plaintiff was only required to submit a CMN to establish the medical necessity and reasonableness of each wheelchair it provided. They further concluded that the Secretary did not have the authority to require that Maximum Comfort provide patient medical records to support medical necessity. A.R. Vol. 2 at 00451; A.R. Vol. 4 at 4.

By notices dated March 21 and November 20, 2001, the MAC notified plaintiff of its determination to review the ALJs' decisions. A.R. Vol. 1 at 21-22; see 20 C.F.R. § 404.969. The MAC's purpose in

reviewing the ALJs' decisions was to determine the type of documentation plaintiff was required to obtain and keep to support the medical reasonableness and necessity of the DME it supplied to Medicare beneficiaries. A.R. Vol. 1 at 21, 24.

On June 11, 2003, the MAC issued its opinion reversing the ALJs' decisions that a CMN is the only required medical necessity documentation and reinstating the denial of reimbursement. Citing § 1834 (j) (2) (B) of the Social Security Act, 42 U.S.C. § 1395m (j) (2) (B), the MAC recognized that Congress established that "a CMN is a form containing information to assist the carrier in determining whether an item is medically reasonable and necessary." A.R. Vol. 1 at 26. It limited the significance of that definition, however, claiming that such language was included only in reference to certain restrictions Congress placed on the type of information that suppliers could provide on the CMN. Id. At 26-27. It then stated that it could not conclude that Congress intended the CMN to be the sole mechanism establishing the coverage of DME, or that the Secretary, through his carriers, cannot establish

additional medical documentation requirements. Id. Based on that reasoning, it concluded that, although plaintiff provided a CMN for each claim, it was also required to submit any other medical necessity documentation as prescribed by the Secretary or his delegates.

The MAC then turned to several manuals and newsletters issued by CIGNA to DME suppliers to determine what medical necessity documents plaintiff was required to provide during the period in question. Adverting to various sections of those materials, it determined that the manuals and newsletters contained pronouncements requiring that plaintiff keep on file and submit beneficiaries' medical records and making it "responsible for [reviewing the records and] making a judgment as to whether the [was] medically necessary." [9] A.R. Vol. 1

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[9] The MAC relied upon language in a March 1997 newsletter, the "DMERC Dialogue-Region D," providing that "a supplier, by virtue of its furnishing a DMEPOS item to a medicare beneficiary, is responsible for making a judgment as to whether the service is medically necessary, and for assigned claims, for informing the beneficiary *prior* to furnishing the item, of the

at 28. Because plaintiff only provided a CMN, the MAC concluded that it failed to meet all documentation requirements. Accordingly, the MAC determined that plaintiff had not provided the required documentation to establish that the wheelchairs were reasonable and medically necessary as contemplated by the Act, and that it had therefore been overpaid by Medicare. A.R. Vol. 1 at 17-39.

III.

STANDARDS

The Medicare Act provides for judicial review of final decisions by the Secretary of Health and Human Services regarding benefits paid under Medicare B. See 42 U.S.C. § 1395ff (a), (b). The reviewing court may affirm, modify, or reverse the final decision of the Secretary. 42 U.S.C. § 405 (g) (incorporated by reference in 42 U.S.C. § 1395ff (b) (1) (a)).

Review of the Secretary's decision is governed

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likelihood of Medicare denial of payment on the basis that the item is not reasonable and necessary." A.R. Vol 1. At 28 (emphasis added).

by the Administrative Procedure Act, 5 U.S.C. §§ 701-706, which provides that the Agency's decision will be set aside only if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law. . .or unsupported by substantial evidence." 5 U.S.C. § 706 (2) (A), (E); see also French Hosp. Med. Ctr. v. Shalala 89 F.3d 1411, 1416 ((9th Cir. 1996). Because the parties agree that the facts are restricted to the administrative record, [10] the sole issue is one of law., i.e. whether the MAC's determination of the scope of a provider's obligation relative to documenting medical necessity is legally proper.

A court's review of an agency's construction of a statute which is charged with administering involves a now familiar two step process. First, it must determine whether the statute speaks directly

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[10] While there are limited circumstances in which the District Court may receive information extrinsic to the administrative record, see Occidental Engineering Co. v. INS, 753 F.2d 766, 769-70 (9th Cir. 1985) (citing Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 415 (1971)), in the matter at bar, there has been no indication by an party that receipt of extrinsic evidence and de novo fact-finding by the court is appropriate.

to the issue; if so, no further construction is required. Chevron U.S.A. Inc. v. Natural Resources Defense Council Inc., 467 U.S. 842. That is because, "[i]f the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress." Id. On the other hand, if the court concludes that "the statute is silent or ambiguous," it must determine "whether the agency's answer is based on a permissible construction of the statute." Id.

The manner in which the agency supplies construction of the statute is within its discretion. Cmty. Hosp. of Monterey Peninsula v. Thompson, 323 F.3d 782, 790 (9th Cir. 2003). Thus, it is not necessary that the agency promulgate regulations, but it may properly determine benefits under the Medicare Act by relying upon both the rule making and the adjudicative process. Id. "It is, thus, well settled that, if the Secretary fills a gap that he is authorized to fill, his resolution in the course of formal adjudication of the kind we review is controlling unless arbitrary, capricious, or manifestly

contrary to the statute." Id. [11] While an agency may construe statutes through the adjudicative process, due process may restrain retroactive application of a construction which adversely affects a provider's right to reimbursement. See Covey v. Hollydale Mobilehome Estates, 116 F.3d 830 (9th Cir. 1997).

IV.

ANALYSIS

The issue tendered is whether the Secretary may required that plaintiff, as a DME supplier, obtain and submit medical documentation in addition to the CMN to prove the medical necessity and reasonableness of the motorized wheelchairs it

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[11] "A decision is arbitrary and capricious if the agency 'has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that is could not be ascribed to a difference in view or the product of agency expertise.' " O'Keeffe's, Inc. v. United States Consumer Prod. Safety Comm'n, 92 F.3d 940, 942 (9th Cir. 1996) (quoting Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins.Co., 463 U.S. 29, 43 (1983)).

supplied to Medicare beneficiaries. [12]

A. THE PARTIES' CONTENTIONS

The Secretary asserts that the MAC correctly concluded that he is vested with the authority to promulgate rules regarding the type of documentation required to determine the medical necessity of DME. He maintains that neither the Medicare Act nor the implementing regulations establish the CMN as the sole document to demonstrate that an item is medically reasonable and necessary. Def's Br. In Supp. Of Mot. For Summ. J. At 15. Rather, he argues, "Congress has granted the Secretary very broad discretion to determine the documentation required to establish medical necessity. . . " Id. at 2. He asserts that it was pursuant to this authority that he required that "[a] CMS must be substantiated by the patient's relevant

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[12] A second issue was whether plaintiff was required to make an independent determination of medical necessity. While that issue is discussed in the body of this opinion, as the court understands it, the MAC's determination of overpayment essentially rested upon the failure to obtain documentation beyond the CMN.

medical records." Def's Supplemental Br. At 4.

The Secretary argues that the court must give deference to the MAC's decision because the medical necessity documentation requirements were created under his authority and are not "inconsistent with the statute or regulations or . . . an unreasonable implementation of them." Def's Br. in Opp'n. To Pl's Mot. For Prelim. Inj. at 16. Accordingly, he claims plaintiff was properly required to obtain the beneficiaries' medical records, review them, and make a judgment as to whether the wheelchairs at issue were medically necessary.

Plaintiff, on the other hand, argues that the MAC's decision improperly imposed documentation requirements, and maintains that its only obligation under the Medicare Act to show that the wheelchairs it provided were medically necessary was to keep on file and provide a CMN. Pl's Br. in Supp. of Mot. for Summ. J. at 4. Plaintiff insists that it abided by this requirement when it sought reimbursement for the motorized wheelchairs by providing CIGNA with a CMN for each claim.

Plaintiff advances two arguments to support

its contention that the Secretary's underlying decision is unfounded. First, it contends that the Secretary simply does not have the authority to create rules or regulations requiring medical necessity documentation in addition to the CMN. Pl's Br. In Supp. of Motion for Summ. J. at 3. Second, it asserts that, even if the Secretary did have the authority, any such rules would not be binding upon it because CIGNA did not provide it with adequate notice of the new documentation requirements.

B. THE SECRETARY'S AUTHORITY

The resolution of this case turns on whether Congress has directly spoken on medical necessity documentation requirements, or whether it explicitly or implicitly delegated the task to the Secretary, vesting him with discretion to establish the challenged requirements. As I explain below, a review of the statute demonstrates that, contrary to the Secretary's contentions, there is no gap left by Congress for the Secretary to fill regarding medical necessity documentation.

To resolve the issues in dispute, I must "look first to the plain language of the statute, construing

the provisions of the entire law, including its object and policy, to ascertain the intent of Congress." Carson Harbor Vill. Ltd. v. Unocal Corp., 270 F.3d 863, 877 (9th Cir. 2001) (en banc) (internal citations omitted). AS the High Court instructed, ' "the meaning of a statute must, in the first instance, be sought in the language in which the act is framed, and if that is plain,. . .the sole function of the courts is to enforce it according to its terms.' " Id. At 878 (quoting Caminetti v. United States, 242 U.S. 470, 485 (1917)).

Put directly, here Congress addressed the issue of medical necessity documentation in 42 U.S.C. § 1395m (j). That section provides that a " ' certificate of medical necessity' means a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395m (j) (2) (B). [13] The

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[13] The Act also specifies what the CMN shall contain:

(2) Certificates of medical necessity

(A) Limitation on information provided by suppliers on

certificates of medical necessity

(i) In general

Effective 60 days after October 31, 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no than the following information completed by the supplier:

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) Information on payment amount and charges

If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (I), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) Penalty

Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (I) or fail to provide the information required under clause (ii) is subject to a civil money penalty in an amount

Secretary's contention that Congress provided him with the authority to decide what documentation may be required to determine the medical necessity of DME conflicts with the plain meaning of § 1395m (j) (2) (B). That section plainly specifies that Congress intended that whatever information may be required by carriers from suppliers to show the medical necessity and reasonableness of DME must be contained in a CMN. As I explain below, the CMN complies with § 1395m (j) (2) (B); moreover, any deficiency in the CMN now in use is easily corrected administratively.

The CMN is created and approved by CMS and is comprised of four sections. Section A solicits identifying information of the supplier, beneficiary, and physician, as well as other administrative

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not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1320a-71 of this title (other than subsections (a) and (b) of such section) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1320a-7a(a) of this title.

42 U.S.C. § 1395m (j) (2) (A).

information. A.R. Vol. 4 at 860-861. Section B contains a series of questions to be completed by the beneficiary's ordering physician. According to the instructions for completing the CMN, Section B "is used to gather clinical information to determine medical necessity." Id. at 861. Section C of the CMN requires the supplier to provide a narrative description of the equipment and the cost thereof. Id. Finally, section D provides for the physician's attestation and signature. Id. at 860. The instructions explain that the physician's signature "certifies the items ordered are medically necessary for [the] patient." Id. at 861. [14] The CMN thus complies with Congress' mandate that whatever clinical information the carrier determines is required to determine the medical necessity of motorized wheelchairs must be gathered using the CMN. Given the above, no room is left for requiring

[14] The physician's signature "certifies that the medical necessity information . . . is true, accurate and complete, . . . and [that the physician] understand[s] that any falsification, omission, or concealment of material fact in [section B] may subject [the physician] to civil or criminal liability." A.R. Vol. 4 at 861.

further documentation.

Despite the Congressional specification of the function of the CMN, the Secretary cites to 42 U.S.C. § 405(a) to support his position that he properly required plaintiff to provide beneficiaries' medical records. I cannot agree.

Section 405(a) provides that the Secretary "shall have full power and authority to make rules and regulations and to establish procedures" to carry out the provisions of the Act. 42 U.S.C. § 405(a). This authority, however, does not mean that he has the authority to create rules that are at odds with the plain language of the statute. Pub. Employees Ret. Sys. of Ohio v. Betts, 492 U.S. 158, 171 (1989) ("[N]o deference is due to agency interpretations at odds with the plain language of the statute itself."). Section 405(a) cannot be read to permit the Secretary to create requirements that undermine both the plain text of the statute and Congressional intent.

Defendant presents three arguments in support of his contention. None are persuasive. First, the Secretary argues that because he is vested with the authority to determine what criteria must be

met for an item to be medically reasonable and necessary, he must also be vested with the authority to determine the mechanisms by which suppliers prove that criteria. Second, he submits that the CMN is not sufficient to provide the required information to demonstrate medical necessity because Congress restricted the type of information that suppliers may provide on it. Lastly, he argues that the plaintiff was required to submit additional medical necessity information because the CMN does not request enough information to address all the criteria for motorized wheelchairs. I address each argument in turn.

The premise of the Secretary's chief argument is that he is authorized to determine the type of medical necessity documentation by virtue of his authority to determine medical necessity criteria. Defendant correctly asserts that Congress granted him broad discretion over the criteria required to prove medical necessity and reasonableness. Nonetheless, as I note below, Congress did not provide the Secretary with the same discretion regarding the type of documentation which suppliers

must provide.

Congress vested exclusive and final authority in the Secretary to decide what criteria must be met for a particular item or service to qualify as medically necessary, and accordingly, to be reimbursable under Medicare. 42 U.S.C. § 1395ff(a); 42 U.S.C. § 1395y(a)(1)(A). 42 U.S.C. § 1395x(n) provides that power-operated wheelchairs may be covered "where the use of such a vehicle is determined to be necessary on the basis of the individual's medical and physical condition. . .as the Secretary may prescribe." In Heckler v. Ringer, the High Court emphasized that "[t]he Secretary's decision as to whether a particular medical [item] is 'reasonable and necessary' " is "clearly" within his discretion. 466 U.S. 602, 617 (1984).

Exercising this authority, the Secretary has promulgated regulations establishing criteria to be used in determining the medical necessity and reasonableness of motorized wheelchairs. Section 410.38 of Title 42 of the C.F.R. provides that wheelchairs must be used in the patient's home or in an institution that is used as a home, that power-

operated wheelchairs must be "necessary on the basis of the individual's medical and physical condition," and "[m]eet any safety requirements specified by CMS." 42 C.F.R. 410.38. The Secretary asserts that the Carrier's manuals and newsletters contain further medical necessity criteria. [15] Def's Br. in Supp. of Mot. for Summ. J. at 6. Specifically, he points to the "DMERC Region D Supplier Manual" issued in December of 1993 which provides that power-operated wheelchairs are covered if: (1) the beneficiary would otherwise be bed or chair confined, (2) the wheelchair is medically necessary and the patient is unable to operate the wheelchair manually, and (3) the beneficiary is capable of safely operating the power wheelchair. Id.; A.R. Vol. 1 at 52. [16]

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[15] The MAC's decision did not discuss the legal sufficiency or weight of the Carrier manuals and newsletters. Given the court's disposition, I need not address that issue.

[16] Plaintiff, quite properly, does not dispute the Secretary's authority or ability to prescribe the medical necessity criteria for the motorized wheelchairs it provided to Medicare beneficiaries.

The Secretary reasons that, because he has prescribed medical necessity criteria for wheelchairs, "providers and suppliers must follow the uniform. . . documentation requirements set forth in [the] carrier issuance. . . . " Def's Br. in Supp. Of Mot. for Summ. J. at 15. He avers that his discretion to determine the medical necessity of an item "includes the right to determine the level of documentation necessary to substantiate that an item of durable medical equipment furnished to a Medicare beneficiary is reasonable medically necessary." Def's Br. in Opp'n to Pl's Mot. For Prelim. Inj. at 5. This analytical leap has some initial appeal, and if Congress was silent, might well be persuasive. The fact is, however, that the argument simply cannot stand in light of the fact that Congress has directly spoken to the issue. Put another way, while it is clear that Congress vested the Secretary with the discretion to determine medical necessity criteria, it does not inexorably follow that Congress concurrently granted him the authority to determine the type of documentation required to satisfy that criteria. Indeed, it is clear that Congress did not do so.

It is true that Congress explicitly provided the Secretary with authority to determine medical necessity criteria. Importantly, however, Congress not only omitted similar language pertaining to medical necessity documentation, it determined this issue itself in creating and defining the CMN, thereby leaving no gap for the Secretary to fill.

"In construing a statute, we begin with the understanding that Congress says in a statute what it means and means in a statute what is says there." In re Price, 353 F.3d 1135, 1140 (9th Cir. 2004) (internal quotations and citations omitted). It is plain from the Medicare Act that Congress meant for the Secretary to determine medical necessity and that the required information to make that determination be contained in a CMN. Accordingly, the plain language of the statute forecloses the Secretary's first argument.

I now examine the Secretary's second argument tendered in support of his position. That argument asserts that §1833 (e) of the Act, 42 U.S.C. § 13951(e), provides the Secretary with the authority to create the disputed medical necessity

documentation requirements in his discretion. Again, I cannot agree.

Section 13951(e) provides that "[n]o payment shall be made to any provider of services. . .under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider. . . ." 42 U.S.C. § 13951(e). The Secretary asserts that the MAC correctly concluded that the requirement that a DME supplier maintain " 'medical documentation[,] in addition to the CMN in the supplier's records, . . . is consistent with §1833(e) of the Act, which requires suppliers to furnish sufficient information to support payments under Part B.' " Def's Br. in Opp'n to Pl's Prelim. Inj. At 15; A.R. Vol. 1 at 29. The Secretary asserts that the statute implicitly grants him the discretionary authority to create medical necessity documentation requirements in order to determine whether a particular item may be reimbursed. The Secretary's focus on the opening language of the section is too narrow. As the balance of the statute demonstrates, the statute's provision addresses "determin[ing] the *amounts* due such provider. . . ."

42 U.S.C. § 13951(e) (emphasis added). Read in its entirety, it is apparent that this section concerns information which the Secretary may require to ascertain the monetary amount due for covered items, and has no bearing on the determination of medical necessity.

The Secretary's reliance on Cmty. Hosp. of Monterey Peninsula v. Thompson, 323 F.3d 782 (9th Cir. 2003), to demonstrate that § 13951(e) provides him with discretion to create medical necessity documentation requirements is unavailing. That decision addressed the means of ascertaining the amount due a provider. The Circuit quite correctly concluded that the plain text made it clear that "Congress expected the Secretary to resolve" billing issues and the requirements placed on providers relative to that issue had been properly created pursuant to his discretionary power. Id. at 789. The court explained that §§ 1395g(a) and 1395x(v) (1) (A) of Title 42 of the United States Code explicitly provided the Secretary with such authority. Id. at 789-790. Those two sections provide that the Secretary shall determine the reimbursement

amount of a given service by, inter alia, considering the cost actually incurred to the provider and establishing methods to be used in computing the amount of payment. [17] In sum, the portion of the Act

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[17] 42 U.S.C. § 1395x (v) (1) (A) provides, in relevant part, that:

> The reasonable cost of any services shall be the cost actually incurred, excluding therefrom any part of incurred cost found to be unnecessary in the efficient delivery of needed health services, and shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included, in determining such costs or various types of classes of institutions, agencies, and services; . . . the Secretary shall consider, among other things, the principles generally applied by national organizations or established prepayment organizations (which have developed such principles) in computing the amount of payment, to be made by persons other than the recipients of services, to providers of services on account of services furnished to such recipients by such providers. . . . Such regulations shall (i) take into account both direct and indirect costs of providers of services (excluding therefrom any such costs, including standby costs, which are determined in accordance with regulations to be unnecessary in the efficient delivery of services covered by the insurance programs established under this subchapter) in order that, under the methods of determining costs, the necessary costs of efficiently delivering covered services to individuals covered by

addressed in Cmty. Hosp. instructs the Secretary to create regulations regarding the determination of the amount due to providers for services and the methods

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the insurance programs established by this subchapter will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by such insurance programs, and (ii) provide for the making of suitable retroactive corrective adjustments where, for a provider of services for any fiscal period, the aggregate reimbursement produced by the methods of determining costs prove to be either inadequate or excessive.

42 U.S.C. § 1395g (a) provides that:

> The Secretary shall periodically determine the amount which should be paid under this part to each provider of services with respect to the services furnished by it, and the provider of services shall be paid, at such time or times as the Secretary believes appropriate. . .and prior to audit or settlement by the General Accounting Office, from the Federal Hospital Insurance Trust Fund, the amounts so determined, with necessary adjustments on account of previously made overpayments or underpayments; except that no such payments shall be made to any provider unless it has furnished such information as the Secretary may request in order to determine the amounts due such provider under this part for the period with respect to which the amount are being paid or any prior period.

by which to make that determination. The Ninth Circuit's opinion, limited to the issue of billing requirements, is clearly distinct from the question presented here. Indeed, Cmty. Hosp. indirectly supports the plaintiff's position.

The sections of the statute at issue in Cmty. Hosp. Are akin to § 13951(e), relied upon by the Secretary here. Like §§ 1395g(a) and 1395x (v) (1) (A), § 13951(e) also explicitly provides the Secretary discretion to determine the monetary amount due to a supplier for qualifying DME. Significantly, however, while Congress vested the Secretary with authority over medical necessity criteria and billing requirements, it did not include language in the Act delegating the same authority concerning medical necessity documentation, but chose to speak on that subject itself. Unlike billing matters, Congress did not leave a gap for the Secretary to fill regarding medical necessity documentation; instead, it specifically provided that whatever information is required to determined the medical necessity of DME is to be contained in a CMN. The Secretary's contention that § 13951(e) provides him with

discretion to create the requirement in question is based on an impermissible reading of the statute.

Lastly, I address the Secretary's claim that it may require that DME suppliers obtain and provide Medicare beneficiaries' medical records because "[i]t is not possible for a CMN to fully describe the medical necessity of DME." Def's Br. In Supp. of Mot. for Summ. J. at 15. The Secretary asserts that because "the Act places strict limitations on the kind of information a supplier may ask a physician to provide in a CMN," beneficiaries' medical records are necessary to substantiate the medical necessity of DME. Id. at 15-16. Below, I explain why the argument fails.[18]

Part B of the Act places limits on suppliers' use of a CMN, but does not in any way restrict the type or amount of medical information that *physicians* may be required to include in it. See 42 U.S.C. § 1395m (j)

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[18] I am compelled to observe that if the Secretary is right, his relief comes not from applying a construction of the statute which is inconsistent with its plain meaning; rather, his relief is to be sought by legislative action.

(2) (A) (I). [19] While the statute provides that the *supplier* cannot complete the portion of the CMN relating to the beneficiary's medical condition, but is

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[19] The statute provides, in pertinent part:

> ". . .a supplier of medical equipment and supplies may distribute to physicians. . . a Certificate of Medical Necessity. . . which contains no more than the following information *completed by the supplier*: (I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished. (II) A description of such medical equipment and supplies. (III) Any product code identifying such medical equipment and supplies. (IV) Any other administrative information (other than information relating to the beneficiary's medical condition) identified by the Secretary. . . ."

42 U.S.C. § 1395m (j) (2) (A) (i) (emphasis added).

strictly limited to providing administrative information, nothing in that section supports the Secretary's argument that Congress limited the type of medical condition information in a CMN that may be provided by others.

The Secretary also argues that plaintiff must obtain, review, and provide medical records to prove the medical necessity of power wheelchairs and other DME. According to the Secretary, Congress placed the limitations listed in § 1395m (j) (2) (A), and created penalties for violations of that section, because of concern with fraudulent and abusive practices by DME suppliers. Def's Br. in Supp. of Mot. for Summ. J. At 15-16; A.R. Vol. 1 at 27. [20] According to the Secretary, these policy considerations place limits on the medical information that a supplier may obtain from a physician on a CMN. On that basis, the Secretary

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[20] Indeed, Congress provided that suppliers who violate the restrictions enumerated in § 1395m (j) (2) (A) (i) are subject to monetary penalties of up to $1,000 per violation. See 42 U.S.C. § 1395m (j) (2) (A) (iii).

contends that he must have the authority to create other documentation requirements so that he may determine when DME may be reimbursed by Medicare, while at the same time being mindful of Congressional intent to curb supplier fraud.

The argument is less than pellucid. I have already noted that the statute does not limit physician-supplied information. Moreover, it is unclear how such policy considerations allow or require that suppliers obtain medical records to support and make a judgment about the medical necessity of DME. The Secretary fails to explain why, if Congress was concerned with supplier misconduct, and accordingly strictly restricted suppliers to providing administrative information, it would agree to allow suppliers to "request copies of the customer's medical and clinical records substantiating the doctor's CMNs and review them for. . . completeness and reasonableness." Def's Br. in Opp'n to Pl's Prelim. Inj. at 12; A.R. Vol. 1 at 28-29. Indeed, it appears to this court that the Secretary's contention based on Congressional concern with suppliers' fraudulent practices is a non sequitur.

Given that Congress designated the vehicle by which suppliers are to provide the information requested by the Secretary to determine medical necessity, and that it took precautionary measures to prevent supplier misconduct, it seems implausible that Congress would allow suppliers to obtain and keep private medical records, second guess physicians' professional conclusions by making medical necessity judgments themselves, and then inform beneficiaries prior to furnishing an item of "the likelihood of Medicare denial of payment." See A.R. Vol. 1 at 29. Such requirements would likely lead to the very type of abuse that apparently concerned Congress. Finally, in this regard, I note that the Secretary's construction raises serious privacy concerns. [21] A construction raising

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[21] Individuals have a right protected under the Due Process Clause of the Fifth and Fourteenth Amendments in the privacy of personal medical information and records. Yin v. State of Cal., 95 F. 3d 864 (9th Cir. 1996); see also Whalen v. Roe 429 U.S. 589, 599 (1977). Moreover, the Privacy Act, 5 U.S.C. § 552a, provides that, with certain exceptions, "no agency may disclose any record which is contained in a system of records. . .except pursuant to a written request by, or with the prior

constitutional questions, or suggesting statutory conflict is, of course, to be avoided.

In a final effort to defend the challenged documentation requirements, the Secretary argues that the plaintiff was required to obtain medical records because the current CMN does not request enough information to provide information as to all of the medical necessity criteria for motorized wheelchairs. Def's Br. in Supp. of Mot. for Summ. J. at 17. According to the MAC, the CMN alone would not have allowed CIGNA to determine the medical reasonableness of the wheelchairs because the document fails to "solicit information concerning all the coverage criteria." A.R. Vol. 1 at 30. Specifically, the MAC explained that, "although the coverage manual states that the patient's condition must be such that without the use of a wheelchair, the patient would otherwise be bed or chair confined, there is no

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written consent of, the individual to whom the records pertains. . . ." 5 U.S.C. § 552a (b); See also Cal. Civ. Code § 56.10(C) (requiring health care providers to hold a patient's medical information confidential unless the information falls under an enumerated exceptions).

question on the CMN that specifically addresses this coverage element." Id. The Secretary further argues that, because plaintiff was on notice of all of the coverage elements and the CMN did not inquire regarding all of them, it should have known that is needed to supply medical documentation in addition to the CMN. [22]

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[22] According to 42 C.F.R. § 411.406 (e) (1), a supplier will be presumed to know that an item was not reasonable and necessary where the supplier has received relevant CMS notices, including manual issuances or other written guides from the Medicare carrier. 42 C.F.R. § 411.406 provides that:

(c) Knowledge based on experience, actual notice, or constructive notice. It is clear that the provider, practitioner, or supplier could have been expected to have known that the services were excluded from coverage on the basis of the following:

(1) Its receipt of CMS notices, including manual issuances, bulletins, or other written guides or directives from intermediaries, carriers, or QIOs, including notification of QIO screening criteria specific to the condition of the beneficiary for whom the furnished services are at issue and of medical procedures subject to the preadmission review by a QIO.

(2) Federal Register publications containing notice of national coverage decisions or of other specifications regarding

The MAC is correct that the CMN used during the time in question and currently in effect, DMERC form 2.03 A, does not make inquiries regarding all of the medical necessity criteria for motorized wheelchairs. See A.R. Vol. 4 at 860. That form asks only seven questions regarding the beneficiary's medical condition and does not inquire whether the patient would be bed or chair confined without a motorized wheelchair, a criterion that must be met for a wheelchair to be considered medically necessary for the beneficiary. Id. At 860. The Secretary essentially argues that his response to this "practical dilemma" is to require suppliers to obtain other medical documentation to provide proof of whatever criteria are not addressed in the CMN.

Although courts may go beyond the plain meaning of a statute if it leads to an "impracticable consequence," the problem complained of here is not a consequence of the statute, but of CMS' drafting of

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noncoverage of an item or service.

(3) Its knowledge of what are considered acceptable standards of practice by the local medical community.

the CMN. As I now explain, because the "problem" is self-created and easily remedied, a proper construction of the statute does not at all produce an impracticable result, and the plain meaning must be honored. See Avendano-Ramirez v. Ashcroft, 365 F. 3d 813, 816 (9th Cir. 2004). That CMS has elected to limit the questions on the CMN does not mean that it is incapable of soliciting all of the necessary information required to make a medical necessity determination based on all the coverage criteria. Indeed, a prior version of the form demonstrates that CMS is capable of meeting Congress' directive by obtaining all of the required medical necessity information on a CMN. That version, DMERC form number 2.01, contained twenty questions covering a wide variety of medical coverage elements, including whether the patient would otherwise be bed or chair confined. Decl. of Tom Lambert, Exh. A. The solution to the current gap between medical necessity coverage criteria and the information solicited on the CMN is not to impose an impermissible requirement that the supplier obtain and review medical records, but to use a CMN similar to DMERC form number

2.01, seeking that information from the physician. The Secretary cannot rest on a self-created problem to justify ignoring the plain words of the statute.

For the foregoing reasons, the court concludes that the plain language § 1395m (j) (2) (A) (i) supports the plaintiff's position that it may only use a CMN to provide the necessary information for the determination of medical necessity and reasonableness. The Secretary cannot require that DME suppliers, such a plaintiff, obtain Medicare beneficiaries' medical records and make a judgment as to whether the equipment is medically necessary and reasonable. It is clear from the plain text of the Medicare Act that, while Congress granted the Secretary broad discretion over medical necessity and billing criteria and procedures, it did not do the same regarding medical necessity documentation. Instead, Congress addressed that issue itself and established that any and all information required from suppliers to make a medical necessity determination must be contained in a CMN. Because the MAC's conclusion, and the Secretary's contentions, conflict with the plain language of the Medicare Act, plaintiff's motion

for summary judgment must be granted.

V.

CONCLUSION

For the foregoing reasons, the court hereby ORDERS as follows:

1. Plaintiff's motion for summary judgment and permanent injunction is GRANTED;

2. Defendant, and his agents, officers, employees, representatives, and all persons acting in concert or participating with him, are ENJOINED from recouping, offsetting or otherwise collecting from plaintiff any alleged overpayments for any of the beneficiaries which are the subject of this action from any amounts due and owing to plaintiff; and

3. Plaintiff is directed to SUBMIT a proposed judgment, including the amount of judgment and supporting calculations and documents, within twenty (20) days from the date this order is filed. Defendant shall file a statement of non-opposition or an opposition to the amounts set forth in the plaintiff's proposed judgment within twenty (20) days after the date recorded on the proof

of service to the proposed judgment.

IT IS SO ORDERED.

DATED: June 28, 2004

/s/
LAWRENCE K. KARLTON
SENIOR JUDGE
UNITED STATES DISTRICT COURT

APPENDIX C

APPENDIX C

42 U.S.C. §1395n(j):

(j) Requirements for suppliers of medical equipment and supplies

(1) Issuance and renewal of supplier number

(A) Payment

Except as provided in subparagraph (C), no payment may be made under this part after October 31, 1994, for items furnished by a supplier of medical equipment and supplies unless such supplier obtains (and renews at such intervals as the Secretary may require) a supplier number.

(B) Standards for possessing a supplier number

A supplier may not obtain a supplier number unless–

(i) for medical equipment and supplies furnished on or after October 31, 1994, and before January 1, 1996, the supplier meets standards prescribed by the Secretary in regulations issued on June 18, 1992; and

(ii) for medical equipment and supplies furnished on or after January 1, 1996, the supplier meets revised standards prescribed by the Secretary (in consultation with representatives of

suppliers of medical equipment and supplies, carriers, and consumers) that shall include requirements that the supplier–

(I) comply with all applicable State and Federal licensure and regulatory requirements;

(II) maintain a physical facility on an appropriate site;

(III) have proof of appropriate liability insurance; and

(IV) meet such requirements as the Secretary may specify.

(C) Exception for items furnished as incident to a physician's service

Subparagraph (A) shall not apply with respect to medical equipment and supplies furnished incident to a physician's service.

(D) Prohibition against delegation of supplier determinations

The Secretary may not issue more than one supplier number to any supplier of medical equipment and supplies unless the issuance of more than one number is appropriate to identify subsidiary or regional entities under the supplier's ownership or

control.

(E) Prohibition against delegation of supplier determinations

The Secretary may not delegate (other than by contract under section 1395u of this title) the responsibility to determine whether suppliers meet the standards necessary to obtain a supplier number.

(2) Certificates of medical necessity

(A) Limitation on information provided by suppliers on certificates of medical necessity

(i) in general

Effective 60 days after October 31, 1994, a supplier of medical equipment and supplies may distribute to physicians, or to individuals entitled to benefits under this part, a certificate of medical necessity for commercial purposes which contains no more than the following information completed by the supplier.

(I) An identification of the supplier and the beneficiary to whom such medical equipment and supplies are furnished.

(II) A description of such medical equipment and supplies.

(III) Any product code identifying such medical equipment and supplies.

(IV) Any other administrative

information (other than information relating to the beneficiary's medical condition) identified by the Secretary.

(ii) Information on payment amount and charges

If a supplier distributes a certificate of medical necessity containing any of the information permitted to be supplied under clause (I), the supplier shall also list on the certificate of medical necessity the fee schedule amount and the supplier's charge for the medical equipment or supplies being furnished prior to distribution of such certificate to the physician.

(iii) Penalty

Any supplier of medical equipment and supplies who knowingly and willfully distributes a certificate of medical necessity in violation of clause (i) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed $1,000 for each such certificate of medical necessity so distributed. The provisions of section 1320a-7a of this title (other than subsections (a) and (b) of such section) shall apply to civil money penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under section 1320a-7a(a) of this title.

(B) Definition

For purposes of this paragraph, the term "certificate of medical necessity" means a form or other document containing information required by the carrier to be

submitted to show that an item is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

(3) Coverage and review criteria

The Secretary shall annually review the coverage and utilization of items of medical equipment and supplies to determine whether such items should be made subject to coverage and utilization review criteria, and if appropriate, shall develop and apply such criteria to such items.

(4) Limitation on patient liability

If a supplier of medical equipment and supplies (as defined in paragraph (5))--

(A) furnishes an item or service to a beneficiary for which no payment may be made by reason of paragraph (1);

(B) furnishes an item or service to a beneficiary for which payment is denied in advance under subsection (a)(15) of this section; or

(C) furnishes an item or service to a beneficiary for which payment is denied under section 1395y(a)(1) ofthis title;

any expenses incurred for items and services furnished to an individual by such a supplier not on an assigned basis

shall be the responsibility of such supplier. The individual shall have no financial responsibility for such expenses and the supplier shall refund on a timely basis to the individual (and shall be liable to the individual for) any amounts collected from the individual for such items or services. The provisions of subsection (a)(18) of this section shall apply to refunds required under the previous sentence in the same manner as such provisions apply to refunds under such subsection.

(5) Definition

The term "medical equipment and supplies" means–

(A) durable medical equipment (as defined in section 1395x(n) of this title);

(B) prosthetic devices (as described in section 1395x(s)(8) of this title);

(C) orthotics and prosthetics (as described in section 1395x(s)(9) of this title);

(D) surgical dressings (as described in section 1395x(s)(5) of this title0;

(E) such other items as the Secretary may determine; and

(F) for purposes of paragraphs (1) and (3)--

(i) home dialysis supplies and equipment (as described in section 135x(s)(2)(F) of this title),

(ii) immunosuppressive drugs (as described in section 1395x(s)(2)(J) of this title),

(iii) therapeutic shoes for diabetics (as described in section 1395x(s)(12) of this title),

(iv) oral drugs prescribed for use as an anticancer therapeutic agent (as described in section 1395x(s)(2)(Q) of this title), and

(v) self-administered erythropoetin (as described in section 1395x(s)(2)(P) of this title).